

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herein.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1, 3-4, 6-17, 20-26, 28-32 and 35-40, 43 and 45 are now pending. Claim 6 has been amended, claim 44 has been cancelled, and claim 45 has been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

**II. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME**

Claim 43 was also objected to as being a substantial duplicate of claim 1. The Office Action indicates that the phrase “contacting the skin of the animal” is identical in scope to the phrase “topically administering to the animal”. Reconsideration and withdrawal of the objection is respectfully requested.

**III. THE ART REJECTIONS ARE OVERCOME**

Claims 1, 9-14, 21-22, 25-26, 28-32, 38 and 43 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Roop et al. (US 6,143,727).

Claims 1, 9-14, 21-22, 25-26, 28-32, 38 and 43 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Carson et al. (US 5,679,647).

Claims 1, 4, 15-17, 20, 23-24, 35-37, 40 and 44 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over either Powell et al. (US 5,877,159 or WO 01/89535) in view of Roop.

Claims 1, 29 and 39 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over either Carson et al. or Roop et al., in view of either Alexander or Li.

The rejections are respectfully traversed.

Applicants respectfully remind the Examiner that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

Furthermore, the Examiner respectfully reminded that for a Section 103 rejection to be proper, there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings to arrive at the claimed invention. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, the Examiner is respectfully reminded that “obvious to try” is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is additionally respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The Examiner is also respectfully reminded that MPEP 2143.01 mandates that for a Section 103 rejection, there must be some suggestion or motivation to modify reference teachings, and, that MPEP 2143.02 further mandates that for a section 103 rejection, there must be a reasonable expectation of success.

Applicants respectfully submit that none of the cited references obtain an immunological response following topical administration of the bacterial vector in the absence of mechanical perforation of the dermis, as is required in the pending claims.

The Examples of the pending application describe the removal of the cornified epithelium prior to administration of the bacterial vector to the outermost portion of the skin.

In contrast, each of Roop, Carson, and Powell (both WO 01/89535 and US 5877,159) describe only the successful administration via alternate routes (i.e., intranasal in US 5,866,159; intragastric intubation in WO 01/89535; intramuscular injection, intranasal, intradermal injection, and types of a MONO-VACC® device in Carson; and skin grafting and DNA-coated microprojectiles in Roop). Nothing in any of the cited references teaches or suggests that administration of a bacterial vector to the outermost layer of skin results in immunization of the animal. That is, even if one of the references includes topical administration in a laundry list of methods of administration, absent actual experimental results showing an immune response as a result of topical administration, meaning to the top of the skin, not through the skin (as in the case of tynes devices and microprojectiles), one of skill in the art would not recognize any expectation of success of a immune response.

Such a distinction has been recognized previously by the Office. Indeed, Applicants respectfully direct the Examiner's attention to related US Patent No. 6,706,693, which contains claims directed to the use of vectors to induce a systemic immune response. The '693 patent was granted over several references by Carson, attesting to the recognized differences between the cited references and the claimed invention.

Accordingly, as none of Carson, Roop, and Powell teach or suggest the use of bacterial vectors topically applied to induce an immune response, the rejections based on these references cannot stand. As each and every art rejection provided in the Office Action rely on Roop, Carson and/or Powell, Applicants respectfully submit that the rejections must therefore be withdrawn.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102(e) and 103(a) are respectfully requested.

#### **IV. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME**

Claims 1, 9-14, 21-22, 25-26, 28-31, 38-39 and 43 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3 of U.S. patent No. 6,706,693. Claims 1, 4, 6, 9-17, 20-26, 28-32, 35-40 and 43-44 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-38 and 93 of copending Application Serial No. 10/346,021. Applicants will consider these rejections, including the possibility of

filing a terminal disclaimer to obviate the rejections, upon the determination of allowable subject matter in the present application.

And, claims 1, 11-13, 25-26, 28-32, 38-39 and 43 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 6-8, 20-21, 23-27 and 33-35 of copending Application Serial No. 10/116,963. Applicants believe that the elections of species between the applications will result the avoidance of this rejection upon the determination of allowable subject matter. Accordingly, this rejection will be considered at such time as the pending claims have otherwise been deemed allowable.

#### **REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner and his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

## CONCLUSION

In view of the amendments, and remarks herein, the application is in condition for allowance. Reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, is respectfully requested.

Respectfully submitted,

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